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Benign Biliary Strictures
Surgery or Endoscopy?

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Objective
This study compared the results of surgery and endoscopy for benign biliary strictures in one institution, over the same period of time and with the same outcome definitions.

Summary Background Data
Surgery is considered the treatment of choice, offering more than 80% long-term success. Endoscopic stenting has been reported to yield similar results and might be a useful alternative.

Methods
In this nonrandomized retrospective study, 101 patients with benign biliary strictures were included. Thirty-five patients were treated surgically and 66 by endoscopic stenting. Patient characteristics, initial trauma, previous repairs, and level of obstruction were comparable in both groups. Surgical therapy consisted of constructing a biliary-digestive anastomosis in normal ductal tissue. Endoscopic therapy consisted of placement of endoprostheses, with trimonthly elective exchange for a 1-year period.

Results
Mean length of follow-up was 50 ± 3.8 and 42 ± 4.2 months for surgery and endoscopy, respectively. Early complications occurred more frequently in the surgically treated group ($p < 0.03$). Late complications during therapy, occurred only in the endoscopically treated group. In 46 patients, the endoprostheses were eventually removed. Recurrent stricturing occurred in 17% in both surgical and endoscopic patients.

Conclusions
Surgery and endoscopy for benign biliary strictures have similar long-term success rates. Indications for surgery are complete transections, failed previous repairs, and failures of endoscopic therapy. All other patients are candidates for endoscopic stenting as the initial treatment.

Benign bile duct strictures represent a significant clinical problem, despite technological developments that have facilitated diagnosis and management. Surgery is often considered the treatment of choice and results in good long-term results in 70% to 90% of patients.[1–4] Endoscopic biliary stenting has been equally successful[5,6] and produces good long-term results in more than 80%. Comparing results of these treatment modalities is difficult, due to differences in patient population, definition

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of response, and length of follow-up between institutions. This nonrandomized study analyzes, retrospectively, the results of surgery and endoscopic biliary stenting at one institution, over the same period and with the same outcome definitions.

PATIENTS AND METHODS

Patient Population

All procedures for benign biliary strictures between 1981 and 1990 were evaluated. Patients with biliary strictures, developed after surgery for biliary stones or trauma were included in this analysis. Patients with benign strictures due to chronic pancreatitis, sclerosing cholangitis, or impacted stones were excluded from the study. Although all patients were managed in close collaboration by surgeons and endoscopists, no formal selection procedure was carried out. Those patients primarily referred to the surgical department were treated surgically and those patients primarily referred to the gastroenterology department were treated endoscopically.

One hundred and one patients with benign biliary strictures were analyzed. Thirty-five patients were treated surgically and 66 by endoscopic stenting. Visualization of the biliary tree was obtained by endoscopic retrograde cholangiography (ERCP) in 88% and by percutaneous transhepatic cholangiography in 12% of patients (Fig. 1). Patient characteristics at presentation, initial trauma, and subsequent repair are presented in Table 1. The stricture was caused by a surgical procedure in almost all patients and recognized instantly in 24% (Fig. 2). The mean interval between initial trauma and referral was 65 ± 17.7 months for the surgically treated group and 53 ± 12.5 for the endoscopically treated group. Symptoms, laboratory results, and radiologic appearance at presentation are shown in Table 2. The laboratory results showed an elevation of alkaline phosphatase in all patients. In the surgically treated group, 23 patients (64%) had elevated bilirubin levels and in the stented group, 31 (47%) had elevations. No statistically significant differences in symptoms, laboratory and radiology were noted between both treatment groups.

Surgery

The aim of all surgical procedures was to obtain a tension-free, mucosa-to-mucosa anastomosis between unscarred bile duct and the proximal intestine. A proximal hepatico-jejunostomy with a Roux-en-Y jejunal loop was done in most cases. When exposure of the stricture required extensive dissection, resection was omitted and an anastomosis with the left hepatic duct was fashioned. No prolonged postoperative stenting was done.

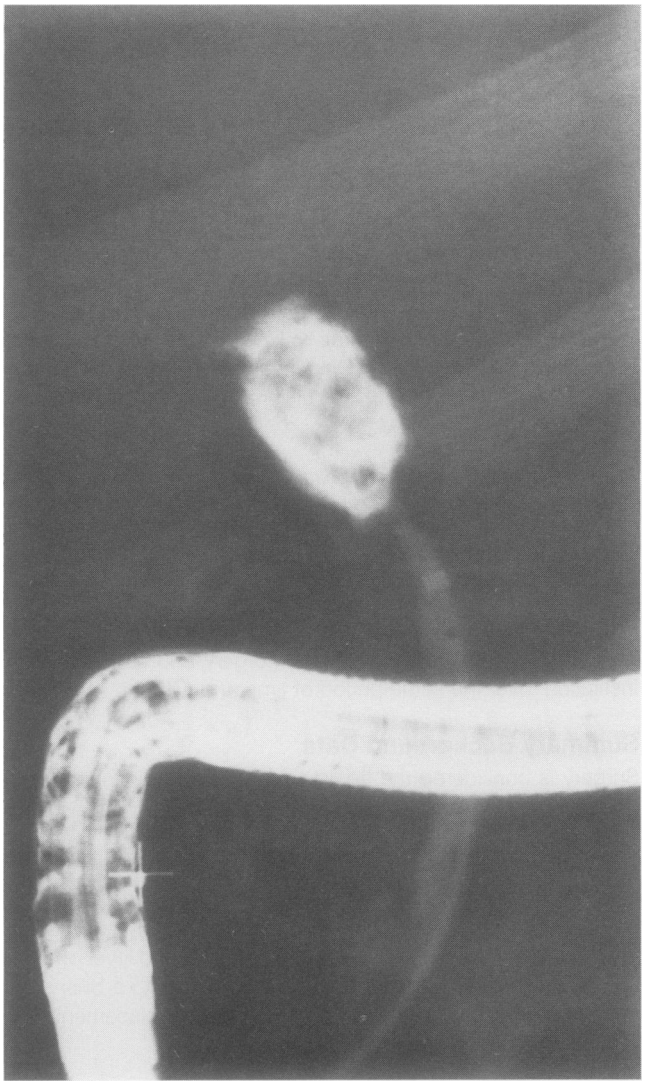

Figure 1. Endoscopic retrograde cholangiogram 18 days after cholecystectomy showing a total bile duct obstruction and some contrast extravasation. Subsequently, a hepaticojejunostomy was performed.

Endoscopic Biliary Stenting

The technique of endoscopic placement of a biliary endoprosthesis has been described in detail elsewhere[7] and briefly consisted of the following steps. After a diagnostic ERCP, a small sphincterotomy was done. Initial dilation was completed, when a tight and firm stenosis prevented passage of a diagnostic catheter. A 10-French gauge (3.2 mm outside diameter) straight polyethylene endoprosthesis was inserted, bridging the narrowed area to obtain a sufficiently wide lumen.

The treatment protocol consisted of initial placement

Table 1. PATIENT CHARACTERISTICS, INITIAL TRAUMA, IMMEDIATE AND LATER SURGICAL REPAIR IN 101 PATIENTS WITH BENIGN BILIARY STRICTURES

	Surgery (N = 35)	Endoscopy (N = 66)
Patient characteristics		
Age (yr)	51 ± 2.8	59 ± 2.0
Range	(22–78)	(19–83)
Female:Male	24:11	32:34
Initial trauma		
Cholecystectomy	20	43
Cholecystectomy and CBD exploration	9	16
CBD exploration	2	2
Cholecystostomy	—	1
Biliary digestive anast.	1	1
Partial liver resection	1	2
Gastrectomy	—	1
Blunt abdominal trauma	1	—
Cholecystitis	1	—
Immediate repair		
Hepaticojejunostomy	2	—
Hepaticoduodenostomy	1	2
Choledochoduodenostomy	2	1
Choledochojejunostomy	1	—
End-to-end anastomosis	1	8
Local repair	1	5
Later repair		
CBD-exploration	—	5
Hepaticojejunostomy	1	—
Choledochojejunstomy	2	—
Choledochoduodenostomy	—	1
End-to-end anastomosis	—	1

of one (7 or 10 Fg) straight endoprosthesis. After 6 weeks, two 10-Fg stents were inserted for a 1-year period, with elective trimonthly exchange to avoid cholangitis (Fig. 3). Antibiotics were administered only when cholangitis was present or successful drainage was not immediately achieved.

Follow-up and Outcome Definitions

Follow-up was accomplished in all patients and obtained by review of hospital records, questionnaire, and telephone interview. All cholangiograms were reviewed to classify the stricture location according to Bismuth.[8]

The results after treatment were classified as follows: an excellent result was defined when the patient was completely asymptomatic with normal or stable liver enzymes, good when only one episode of cholangitis had occurred, and poor when 2 or more episodes of cholangitis or recurrent stricture had occurred.

Statistical Analysis

All data are presented as mean ±SEM (standard error of the mean). Nominal variables were subjected to statistical analysis, using the Chi-square test with Yates correction when appropriate. For non-parametric analysis the Mann-Whitney-U test was performed. All comparisons were two-tailed. Cumulative bile duct patency rate after treatment was calculated by life table analysis according to Kaplan and Meier,[9] supplemented by the log-rank test for comparisons. Probability (p) values less than 0.05 were considered to be statistically significant.

RESULTS

Surgery

The types of biliary reconstruction performed were Roux-en-Y hepaticojejunostomy (N = 26), Roux-en-Y intrahepatic cholangio-jejunostomy (N = 5), Roux-en-Y choledochojejunostomy (N = 2), choledochoduodenostomy (N = 1) and left hemihepatectomy (N = 1).

Early postoperative complications (Table 3) occurred in nine patients (26%). In two patients major hemorrhage required surgical intervention. Both patients bled at the site of the anastomosis, requiring relaparotomy to

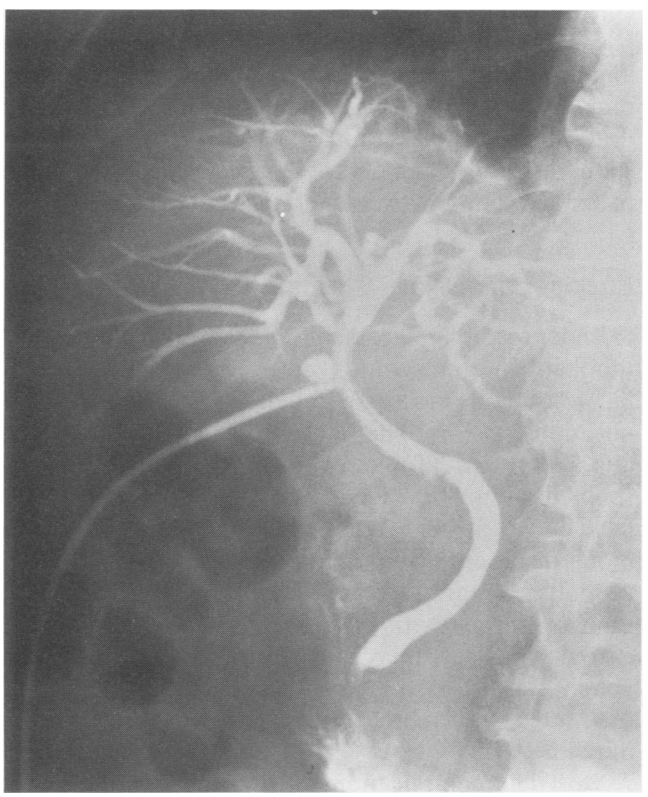

Figure 2. Left: Postoperative T-tube cholangiogram after end-to-end anastomosis of a bile duct lesion during cholecystectomy.

Table 2. PRESENTATION, LABORATORY, AND RADIOLOGY RESULTS IN 101 PATIENTS WITH BENIGN BILIARY STRICTURES

	Surgery (N = 35)	Endoscopy (N = 66)
Presentation		
Jaundice	18 (51%)	33 (50%)
Cholangitis	14 (40%)	21 (32%)
Cholestasis	3 (9%)	12 (18%)
Laboratory results*		
Alk phosphatase (μmol/L)	438 ± 59.2	355 ± 41.9
Range	(28–1584)	(70–1514)
Bilirubin (μmol/L)	64 ± 13.7	81 ± 11.0
Range	(3–286)	(10–284)
Stricture location		
Bismuth 1 (>2 cm CHD)†	10 (29%)	30 (45%)
Bismuth 2 (<2 cm CHD)	14 (40%)	25 (38%)
Bismuth 3 (bifurcation)	4 (11%)	4 (6%)
Bismuth 4 (hepatic ducts)	7 (20%)	7 (11%)
Bismuth 5 (right branch)	—	—
Biliary fistula	4 (11%)	15 (23%)

* Normal values: alkaline phosphatase 60 U/L; bilirubin 17 μmol/L.
† Common hepatic duct.

evacuate a hematoma in one and revision of the hepaticojejunostomy in the other. Five patients had a period of bacteremia due to an abscess (N = 5). One subphrenic and one abdominal abscess, resolved after percutaneous drainage; in two other patients a wound abscess was drained successfully. Finally, a pelvic abscess resolved spontaneously. Temporary bile leakage occurred in two patients responding well to conservative treatment.

Endoscopic Biliary Stenting

Endoprosthesis placement was successful after a mean number of 1.2 procedures (range 1–7). Pre-insertion dilatation was necessary in 15 patients (21%). Early complications (within 30 days) occurred in five patients (8%) and comprised (Table 3): minor bleeding from the sphincterotomy site in one patient and procedure-related cholangitis in two patients responding well to antibiotic treatment. Mild pancreatitis, defined as an elevation of serum amylase of at least three times the upper limit of normal with typical signs and symptoms, occurred in one patient. A laparotomy was done in another patient because of severe pancreatitis. This patient eventually died of a cerebrovascular accident 25 days after the initial ERCP.

Most late complications during the stenting period (> day 30) were due to clogging of the endoprostheses. Late complications included: one episode of cholangitis (N = 4), two or more episodes of cholangitis (N = 10) and recurrent cholestasis (N = 2). Stent exchange relieved the symptoms in all patients. In two patients, stent migration occurred.

In six patients, a Roux-en-Y hepaticojejunostomy was done because of failed complete drainage in four patients, stent migration in one patient, and personal preference in one patient. Four of these procedures were done in our institution.

Six patients died during the endoscopic treatment period. The causes of death were all non-biliary related and included cardiac infarction (N = 3), prostate cancer (N = 1), cerebrovascular accident (N = 1), and urosepsis (N = 1). In eight patients, the endoprostheses were still *in situ* at the time of evaluation. In 46 patients, the endoprostheses were eventually removed.

Follow-up After Surgery

A mean period of follow-up of 50 months (range, 10–85) was available after surgery. In 29 patients (83%), an excellent (N = 25) or good (N = 4) result was achieved. Recurrent stricturing occurred in 6 patients (17%) after a mean period of 40 months (range, 5–81, Table 4). Four patients with a hepaticojejunostomy restrictured after 22, 36, 36, and 60 months, respectively, and both patients with a choledochojejunostomy after 5 and 81 months, respectively (Fig. 4). At reoperation, a proximal hepatico-jejunostomy was done in all with good results until the time of evaluation. Two patients died of nonbiliary-related causes. Potential risk factors such as age, sex, interval between initial trauma and referral, presenta-

Table 3. COMPLICATIONS AND 30-DAY MORTALITY IN 101 PATIENTS WITH BENIGN BILIARY STRICTURES

	Surgery (N = 35)	Endoscopy (N = 66)
Early complications*		
Major hemorrhage	2	0
Minor hemorrhage	0	1
Bacteremia	5	2
Pancreatitis	0	2
Bile leakage	2	0
Subtotal	9 (26%)	5 (8%)†
30-day mortality	0	1
Complications during treatment		
Cholangitis	—	14
Recurrent cholestasis	—	2
Stent migration	—	2
Subtotal		18 (27%)
Total complications	9 (26%)	23 (35%)

* Within 30 days.
† $p < 0.03$.

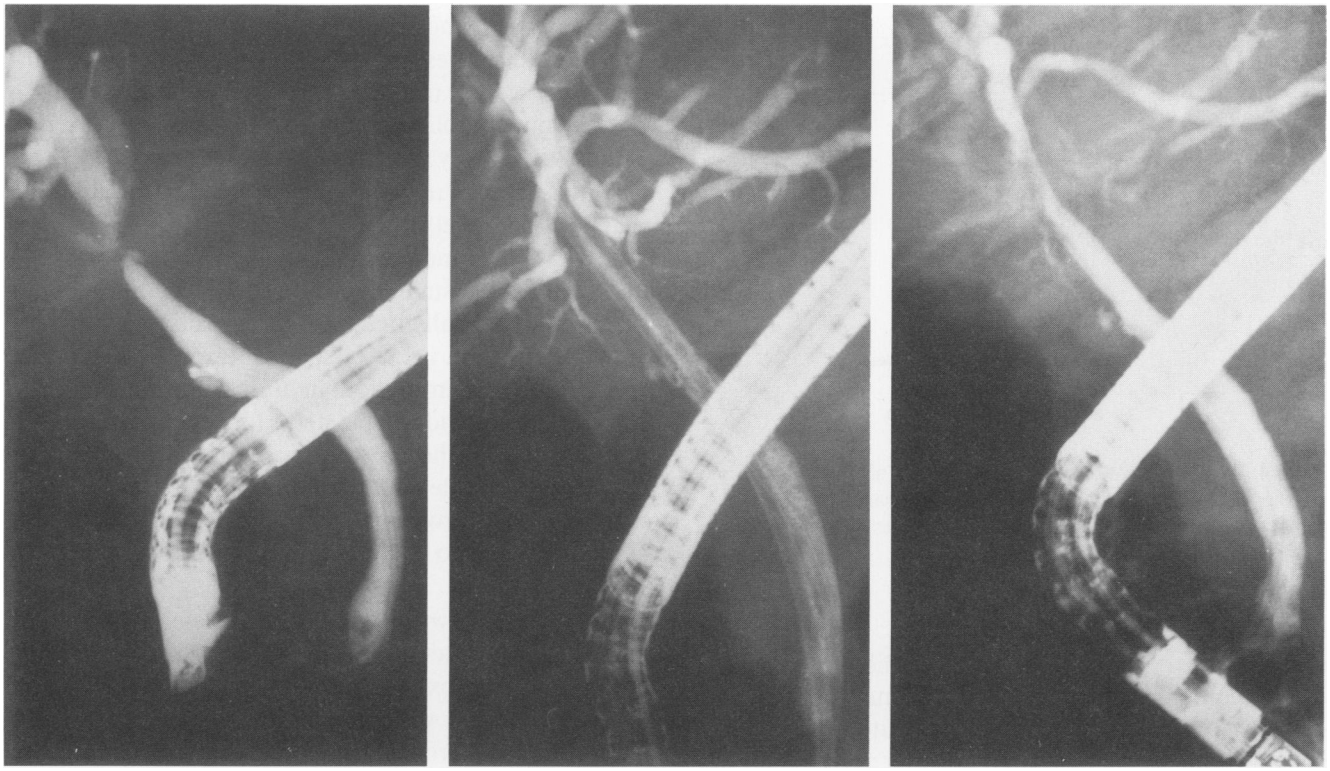

Figure 3. Left: Same patient as in Figure 2. Benign biliary stricture (Bismuth II) 9 months after cholecystectomy, end-to-end anastomosis and T-tube placement. Middle: After endoscopic insertion of two 10-Fg endoprostheses. Right: Sufficient dilation of the stricture after stenting for a 1-year period.

tion, number of previous repairs, type and level of obstruction did not correlate with outcome.

Follow-up After Endoscopic Stenting

In 46 patients, the endoprostheses were removed after a mean period of 360 days (range, 91–725). During this period, a mean number of 5 ERCPs (range, 3–12) were done in each individual. After final removal of the prostheses, the stricture was considered to be sufficiently dilated because of easy passage of a 1-cm balloon through the stricture or because of rapid contrast emptying of the intrahepatic biliary tree seen at fluoroscopy.

After stent removal and a mean follow-up period of 42 months (range 4–99), an excellent (N = 33) or good (N = 5) result was achieved in 38 patients (83%). Recurrent stricturing occurred in 8 patients (17%) after a mean period of 3 months (range 2–30, Fig. 4).

Subsequently, six patients underwent a Roux-en-Y hepaticojejunostomy (four in our institution) and a mean period of follow-up of 46 months (range, 8–84) was available in all. Four had an excellent outcome and two had repeated surgery for stricturing at the site of the hepaticojejunostomy. The remaining two patients, in whom endoscopic treatment was not successful, were re-stented. A mentally retarded patient remained free of cholangitis after placement of two endoprostheses. A 71-year-old man, died of a myocardial infarction 3 months after being re-stented.

Extraction of recurrent gallstones, which had formed above the relative stenosis, was necessary in two patients. Six patients died after stent removal due to nonbiliary-

Table 4. FOLLOW-UP AFTER TREATMENT IN 81 PATIENTS WITH BENIGN BILIARY STRICTURES

	Surgery (N = 35)	Endoscopy (N = 46)
Follow-up in months	50	42
Range	(10–85)	(4–99)
Outcome		
Excellent	25	33
Good	4	5
Poor	6	8
Interval treatment restricturing in months	40 ± 11.0	3 ± 11.2*
Range	(5–81)	(2–30)
Deaths†	2	6

* $p < 0.04$.
† All non-biliary related.

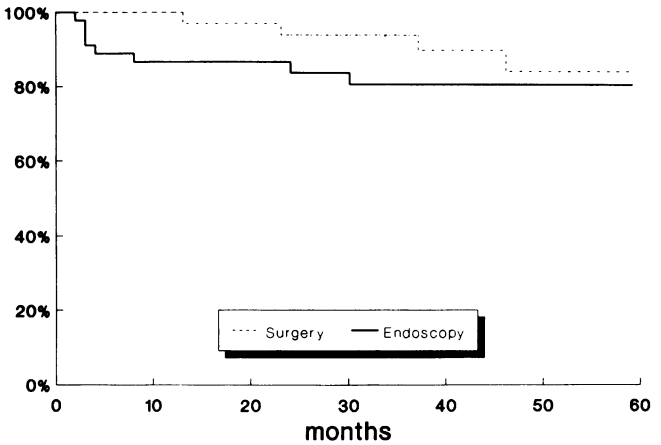

Figure 4. Cumulative bile duct patency rates after surgery (N = 35) and endoscopy (N = 46) in 81 patients with benign biliary strictures. X-axis: percentage of patients with a patent bile duct. Y-axis: follow-up period in months.

related causes. Potential risk factors did not correlate with outcome. In addition, statistical analysis of factors predictive of a more or less favorable outcome after surgical and endoscopic treatment together revealed no significant differences.

DISCUSSION

The majority of bile duct strictures are caused by accidental surgical trauma during cholecystectomy.[10] While the incidence of duct injuries during open cholecystectomy is around 0.1%,[11] reports suggest that injuries of the bile duct during laparoscopic cholecystectomy are five to ten times more frequent.[12] At present, hepaticojejunostomy with Roux-en-Y reconstruction is considered to offer the best possibilities for long-term success in more than 80% of the patients.[1,13,14]

Endoscopic biliary stenting offers similar success rates.[5,6,15,16] However, comparing surgery and endoscopy is difficult due to differences in parameters that might influence outcome. In this study, the results of surgery and endoscopic biliary stenting were compared at the same institution, over the same period and with the same outcome definitions. All patients were managed by one group of surgeons and endoscopists. The outcome definitions were agreed on among the authors before evaluation.

In this study, both treatment groups were remarkably similar; no statistically significant differences were noted with regard to factors that might have influenced the ultimate outcome. Comparing complications was difficult because surgery is a on-off procedure and endoscopic stenting represents a sequence of procedures. Both treatment modalities had equal overall morbidity and mortality rates. Early complications were encountered significantly more in the surgically treated group ($p < 0.03$), but complications during treatment occurred in the endoscopically treated group only.

Some surgeons use transhepatic stenting for at least a year postoperatively in difficult cases, e.g., when the anastomosis is performed at the level of the hilum and when the bile ducts are small.[1,17,18] Long-term stenting was not used in the surgically treated group because the presence of a foreign body, i.e., a biliary stent, induces a chronic proliferative inflammation in unscarred bile duct tissue.[19] However, endoscopic stents for benign biliary strictures can dilate the stricture and allow maturation of already scarred bile duct tissue. The optimal duration of stenting is controversial. This study indicates that beyond 1 year, no more benefit is to be expected with stenting.

Prolonged follow-up is necessary to determine the true recurrence rate after surgery.[2,20] In this analysis, a follow-up period of approximately 4 years was available. A good or excellent result was achieved in 83% in both surgery and endoscopy groups. After endoscopic stenting, restricturing occurred after a significantly shorter interval, than following surgery ($p < 0.04$). In contrast with other studies[2,20,21] we could not identify factors indicating a more or less favorable outcome in relation with either procedure.

Percutaneous transhepatic balloon dilatation has been used in several studies with a success rate of 40 to 85% after a mean follow-up of 16 to 59 months.[1,22–27] The main risk of the transhepatic approach, however, relates to liver puncture with hemorrhage and bile leakage, favoring the endoscopic approach.[28] Two-third of the patients have a nondilated biliary tract,[29] making puncturing a more tedious procedure. In addition, the need to have a transhepatic tube in place for many months is another major disadvantage. Intermittent postoperative balloon dilatation through a choledochojejuno(sub)cutaneous fistula has also been advocated.[30,31] This approach might be an option in highly selected cases.

Surgery or endoscopic biliary stenting for benign biliary strictures are equally successful. However, when endoscopy is not successful, surgery is still feasible, but the reverse sequence is difficult when no access loop is available. Indications for surgery are complete transections, unsuccessful previous repairs and unsuccessful endoscopic therapy. Candidates for endoscopic stenting are those unfit for surgery or presenting with concomitant biliary fistula. In all other patients, the choice for surgery or endoscopy will rely on local expertise. We advocate endoscopic therapy as the initial treatment for benign biliary strictures.

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